

REMARKS

Claims 1-34 are pending and stand rejected. Claims 1, 4, 7, 8, 12, 13, 18, 19, 21, 23, 26, 27, and 28 were rejected under 35 U.S.C. §112 as being indefinite. Claims 1-5, 7-10, 27, and 29-34 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,690,691 to Chen. Claims 1-5, 7-10, 27, and 29-34 were rejected under 35 U.S.C. §102 as being anticipated by U.S. Patent No. 6,327,503 to Familoni. Claims 6, 11-26, and 30 were rejected under 35 U.S.C. §103(a) as being unpatentable over Chen and further in view of U.S. Patent No. 6,892,278 to Gordon. Claim 28 was rejected under 35 U.S.C. §103(a) over Chen and further in view of Gordon or in view of Gordon and U.S. Patent No. 5,188,104 to Wernicke. The rejections as they may apply to the claims presented herein are respectfully traversed.

The Office Action stated that a listing of references in the Specification is not a proper Information Disclosure Statement and will not be considered by the Examiner. However, the Applicant notes that the present application is a continuation application and the references were submitted in an IDS in the proper form in the parent application (Application Serial No. 09/963,149). According to the MPEP, references submitted in an IDS in the parent of a continuation application will be considered. See MPEP §609. Applicants respectfully request that these references be considered by the Examiner and so noted in the next communication from the Examiner.

Turning now to the rejections under 35 U.S.C. §112, Claim 1 was rejected because the term "the stimulator" was allegedly unclear and the term "an analysis" was allegedly vague. Although the Applicants disagree, claim 1 has been amended. More specifically, claim 1 has been amended to recite "implantable gastric stimulator" to clarify what is meant by "stimulator." Claim 1 has also been amended to clarify that an analysis is performed based upon the sensed intrinsic gastric activity.

Claim 4 was rejected under 35 U.S.C. §112 based upon the term “comprises.” The Office Action suggested amending the claim to recite “further comprises.” The suggested amendment has been made by the Applicant. The claim was also rejected because the term “said remote programmer” lacked antecedent basis. The claim has been amended to provide the antecedent basis.

Claims 7 and 8 were rejected under 35 U.S.C. §112 because the term “for identifying” was allegedly unclear. Claims 7 and 8 have been amended to recite that the identifying occurs at the implantable gastric stimulator.

Claims 12 and 13 were rejected under 35 U.S.C. §112 because the term “normal events” lacked antecedent basis. Claims 12 and 13 have been amended to recite “a plurality of normal events” thereby providing antecedent basis.

Claim 18 was rejected under 35 U.S.C. §112 because the term “the temporal offset” lacked antecedent basis. The claim has been amended to provide antecedent basis.

Claim 19 was rejected under 35 U.S.C. §112 because the term “the temporal delivery” lacked antecedent basis. The claim has been amended to provide antecedent basis.

Claim 20 was rejected under 35 U.S.C. §112 because the term “the polarity of the stimulation electrodes is programmable by the user” did not recite the device that is used to perform the programming. The claim has been amended to indicate the stimulator is the device that is used to perform the programming.

Claim 21 was rejected under 35 U.S.C. §112 because the term “the stimulator is programmed by the user” was allegedly vague and “reads like a method step.” The Office Action suggesting deleting “by the user.” The amendment has been made to the claim.

Claim 23 was rejected under 35 U.S.C. §112 as being vague because of the recitation of the term “method.” The term “method” has been changed to “system.” Claim 23 was also rejected because the term “two or more capacitors” was not set out in the claim. The

claim has been amended to set out the element “two or more capacitors.” Claim 23 was further rejected because the term “the array” as used in the second line of the claim was allegedly unclear. The claim has been amended to recite that the arrays recited in the claim refer to the same array.

Claim 26 was rejected under 35 U.S.C. §112 because the terms “the sensed intrinsic waveforms” and “the external programmer” lacked antecedent basis. The claim has been amended to provide the antecedent basis. The claim was also rejected because it was unclear as to which element performed the function of telemetering the sensed waveform. The claim has been amended to recite that the implantable gastric stimulator performs this function.

Claim 27 was rejected under 35 U.S.C. §112 because the term “may” was allegedly vague. The claim has been amended to remove this term. The claim was also rejected because it was allegedly vague as to which element the recited “channels” were connected. The claim has been amended to recite that at least one independently programmable stimulation channel is coupled to the plurality of stimulation electrodes, and at least one independently programmable sensing channel is coupled to the plurality of sensing electrodes.

Applicants respectfully submit that all the rejections under 35 U.S.C. §112 have been overcome and respectfully request that these rejections be withdrawn.

Turning now to the rejections under 35 U.S.C. §102 and 35 U.S.C. §103, amended claim 1 recites a plurality of sensing electrodes for sensing intrinsic gastric activity from the stomach wall of a patient. An implantable gastric stimulator is coupled to the plurality of sensing electrodes, receives the sensed intrinsic gastric activity, performs an analysis of the sensed intrinsic gastric activity, and determines whether to create an electrical stimulation based at least in part upon the analysis of the sensed intrinsic gastric activity. A plurality of stimulation electrodes conveys the electrical stimulation from the implantable

gastric stimulator to the stomach wall of the patient. This electrical stimulation disrupts *normal* gastric activity of the stomach.

The Specification describes various distinctions between normal and abnormal gastric activity. For example, the Specification describes that normal contractions of the stomach have neural control, myogenic control, and slow wave components. Specification, page 3, lines 1-20. To give one example, the Specification mentions that normal slow wave components normally occur at frequencies of from 2-4 cycles per minute. *Id.*

Additionally, the Specification describes that normal gastric activity is discernable from abnormal gastric activity based upon a number of factors. For example, differences in measured pulse amplitudes, pulse widths, and frequency may be used to distinguish between normal and abnormal gastric activity. *Id.* at page 15, lines 18-20 and FIG. 9 and 10. As a result and as described in the Specification, normal and abnormal gastric activity are distinct from each other, have distinct characteristics, and not arbitrarily defined.

In contrast to the subject matter of claim 1, the Chen reference teaches the use of a portable or implantable gastric pacemaker 10. Chen is directed to phased stimulation that is made through a plurality of stimulation electrodes 42, 44, and 46. Chen, col. 5, line 49- col. 6 line 10. After the stimulation is made, Chen employs sensor electrodes 52, 54, and 56 to detect *the electrical response* of an organ where the stimulation was applied. *Id.* Chen does not sense any intrinsic gastric activity of the stomach as recited in claim 1. Further, Chen does not disrupt any gastric activity—normal or abnormal—also as recited in claim 1.

The Familoni patent is directed towards an implantable gastric stimulator for sensing abnormal activity of the gastrointestinal track so as to provide electrical stimulation for a preset time period in order to treat gastric rhythm abnormalities. Specifically, the Familoni system detects whether *abnormalities* such as gastric arrhythmia, bradygastria, dysrhythmia, tachygastria, retrograde propagation and retrograde uncoupling are present in the patient.

Familoni patent, col. 3, lines 44-6. If these abnormalities are present, electrical signals are created to treat the abnormality. *Id.* at col. 3, lines 46-51. Familoni is silent as to ***disrupting any normal gastric activity*** to treat the abnormality.

The Office Action stated that “[i]t is noted that classifying an activity as normal is itself arbitrary.” The Office Action went on to state that various abnormal events in Familoni could be considered “normal” activity. The Applicant respectfully disagrees with these assertions.

Specifically, as mentioned above and described in the Specification, normal and abnormal gastric activity are distinct from each other, have distinct characteristics, and not arbitrarily defined. Furthermore, also as mentioned above, Familoni specifically teaches that the “triggers” correspond to abnormal activity. See Familoni patent, col. 3, lines 44-51.

As for Wernicke, the system described therein senses the amount of food intake (i.e., by detecting the amount of swallowing) and applies a signal to the patient’s vagus nerve. See Wernicke, col. 10, lines 29-64. As for Gordon, a neuromuscular stimulator is described where a current is applied to tissue and a resultant voltage is sensed. See Gordon abstract. Neither reference teaches the sensing of intrinsic gastric activity or the disruption of normal activity as recited in claim 1.

Since claim 1 recites elements not taught or suggested by any of the cited references, it is believed that claim 1 is allowable. Claims 2-28 depend directly or indirectly upon claim 1. Since claim 1 is allowable, it is believed that claims 2-28 are also allowable.

Independent claim 29 has recitations similar to those of claim 1 and it is believed that claim 29 is allowable for the same reasons as those given for claim 1. Claims 30-34 depend directly or indirectly upon claim 29 and it is believed that claims 30-34 are allowable for the same reasons as those given for claim 29.

U.S. Patent Application No. 10/782,087
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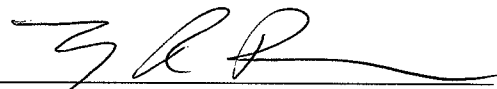
Attorney Docket No. 82391 (6328)

Reconsideration and allowance of the application, as amended, are respectfully requested. In view of the foregoing, it is submitted that the application is in condition for allowance which is respectfully requested.

Respectfully submitted,

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